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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,273	02/07/2006	Lynne E Maquat	21108.0023U2	4987

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EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	
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03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,273	MAQUAT, LYNNE E	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-73* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 2-22-05.

Claims 1-73 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to methods of treating a disorder in a subject, classifiable in class 514, subclasses 1, 2 and 44.

II. Claims 14-29 and 31-36, drawn to methods of screening for substances that modulate nonsense mediated mRNA (NMD) decay complexes, classifiable in class 435, subclass 6, and class 436, subclass 501.

III. Claim 30, drawn to methods of screening for modulating substances comprising incubating a substance with a stably transfected cell, classifiable in class 435, subclass 6.

IV. Claim 37, drawn to methods of screening for modulating substances comprising administering a substance to a system, classifiable in class 424, subclass 9.1.

V. Claim 38, drawn to a method of modulating nonsense mediated mRNA decay activity, classifiable in class 435, subclass 375.

VI. Claim 39, drawn to a method of making a substance capable of modulating nonsense mediated mRNA decay activity, classifiable in class 436, subclass 547.

VII. Claim 41, drawn to a method of making a substance capable of modulating nonsense mediated mRNA decay activity comprising administering a substance to a system, classifiable in class 424, subclass 9.2.

VIII. Claims 40, 42-73, drawn to a substances that modulate NMD, classifiable in class 536, subclass 24.5, class 530, subclasses 300 and 350.

- Applicant is additionally required to elect a single mutation with the elected Group (claims 5, 6).
- Applicant is additionally required to elect a single disorder with the elected Group (claims 2, 3, 4, 7, 8).
- Applicant is additionally required to elect a decrease or increase in NMD with the elected Group (claims 10, 11, 14).
- Applicant is additionally required to elect a single combination of substances with the elected Group (claims 15-29).
- Applicant is additionally required to elect a single substance with the elected Group (claims 43-73).

PLEASE NOTE: THESE ARE NOT SPECIES ELECTIONS.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of screening, modulation, treatment and making

substances are unrelated as they comprise distinct steps, have different biological outcomes and utilize different and distinct products, which demonstrates that each method has a different mode of operation. The methodology and materials necessary for each of these distinct methods differ significantly: methods of screening for modulators that modulate NMD complexes in a test tube (Group II), using a stably transfected cell (Group III), methods of screening for modulators that modulate NMD complexes in a system (Group IV), diagnosis (Group IV), and methods of modulation in vitro (Group V) or in a system (Group VII), and methods of treatment (Group I) each involve distinct steps which are not included in the other methods, and involve different biological outcomes, as well as requiring the administration of different and distinct compounds and compositions, and each involve distinct steps of measurement of different phenomena and phenotypes that are not present in the other Groups.

The different nucleic acid sequences, modulators, polypeptides and target molecules utilized in these different methods claimed constitute chemically, biologically and functionally different and distinct molecules or chemical entities. Therefore, each method is divergent in materials and steps. For these reasons the inventions of I-VII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches, each requiring a separate search for the steps and molecules involved in the various methods steps. The searches required for each of the methods would not be coextensive with each other. For these reasons, it would be burdensome to search the

inventions of Groups I-VII together, and including each of the nucleic acid or polypeptide sequences and modulators claimed.

Searching the inventions of Groups I-VII together would impose a serious search burden. In the instant case, the search of each of the different polynucleotides, polynucleotides or target sequences and modulators is not coextensive with the other, and a search of one type of method will not be coextensive with the search of the other methods. In cases such as this one, where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is a search burden also in the non-patent literature. Similarly, there may have been classical genetics papers that had no knowledge of the screening, treatment or other approaches claimed, but spoke to the genes or agents for evaluation. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups I - VII together.

The different inventions drawn to different molcules are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different molecules, disorders, mutations and substances, and/or methods comprising them are biologically, structurally and functionally different and distinct from each other. The methods involving the use of distinct molecules with distinct activities and biological outcomes and therefore utilize different and distinct compositions, and so utilize distinct methods

steps from each other. For these reasons, the inventions of these different Groups are patentably distinct.

Inventions comprising the different combinations of molecules (listed in claims 15-29 and 31) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the presence of the claims to the combination of various and distinct subcomponents of the substances, ranging from two through fourteen components, and listed in various subcombinations in claims 15-29, is evidence that the details of the first subcombination are not required for patentability and vice versa. The subcombination has separate utility such as molecular weight markers or as enzymes.

Furthermore, when two or more subcombinations are separately claimed along with a claimed combination the presence of each subcombination claim may be used as evidence that the combination does not require either subcombination for its patentability.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in

accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I, V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, treating the various disorders claimed can be carried out with a large number of therapeutic agents and is not limited to the modulators claimed. In addition, the different products can be used as molecular weight markers, or as controls for various assays, including immunological and binding assays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**

otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of

a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
2-29-08
/Jane Zara/

Primary Examiner, Art Unit 1635